Byron Mallott Lieutenant Governor State Capitol Juncau, Alaska 99811 907.465.3520 465.5400 Fax WWW.LTGOV.ALASKA.GOV



530 West 7th Ave, Suite 1700 Anchorage, Alaska 99501 907.269.7460 269.0263 LT.GOVERNOR@ALASKA.GOV

OFFICE OF THE LIEUTENANT GOVERNOR ALASKA

MEMORANDUM

TO:	Jun Maiquis Department of Commerce, Community & Economic Development
FROM:	Scott Meriwether, Office of the Lieutenant Governor 465.4081
DATE:	June 9, 2017
RE:	Filed Permanent Regulations: Board of Pharmacy
	Board of Pharmacy regulations re: pharmacist interns, prescription drug order records, facility standards, patient counseling, and administration of vaccines or related emergency medication (12 AAC 52.120(b)(3)(A); 12 AAC 52.210(1); 12 AAC 52.320(e); 12 AAC 52.400; 12 AAC 52.450; 12 AAC 52.460(a)(9)-(11); 12 AAC 52.500; 12 AAC 52.585(a); 12 AAC 52.992)

Attorney General File:	JU2017200015
Regulation Filed:	6/9/2017
Effective Date:	7/9/2017
Print:	223, October 2017

cc with enclosures:

Linda Miller, Department of Law Judy Herndon, LexisNexis

ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached nine pages of regulations, dealing with requirements for a pharmacy intern license, pharmacist duties, continuing education requirements for a pharmacist administering vaccines or related emergency medications, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and establishing standards for the independent administration of vaccines and related emergency medications, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its March 2-3, 2017 teleconference meeting, under the authority of AS 08.01.075, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.116, AS 08.80.147, AS 08.80.157, AS 08.80.165, AS 08.80.168, AS 08.80.261, AS 08.80.330, and AS 08.80.480 and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

On the record, in considering public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes described in this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

DATE: March 3rd 2017 North Pole, Alaska

Leif Holm, PharmD., Chairman Board of Pharmacy

FILING CERTIFICATION

I, Byron Mallott, Lieutenant Governor for the State of Alaska, certify that on ______, 2017 at _____, m., I filed the attached regulations according to the provisions of AS 44.62.040 - 44.62.120.

Byron Mallott, Lieutenant Governor

Effective: July 9, 2017. Register: 223 October 2017

Chapter 52. Board of Pharmacy.

12 AAC 52.120(b)(3)(A) is amended to read:

(A) enrolled [COMPLETED THE FIRST YEAR OF A

PROFESSIONAL PHARMACY CURRICULUM] in a college of pharmacy accredited by the ACPE; or



(Eff. 1/16/98, Register 145; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am

1/17/2007, Register 181; am 11/16/2012, Register 204; am <u>7/9/2017</u>, Register 223)

 Authority:
 AS 08.80.005
 AS 08.80.110
 AS 08.80.116

AS 08.80.030

12 AAC 52.210(1) is amended to read:

(1) receiving an oral prescription drug order [, INCLUDING REFILL APPROVAL OR DENIAL THAT INCLUDES ANY CHANGE TO THE ORIGINAL PRESCRIPTION DRUG ORDER];

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.320 is amended by adding a new subsection to read:

(e) A pharmacist administering a vaccine or related emergency medication under

12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section. (Eff. 1/16/98,

Register 145; am 5/5/2000, Register 154; am <u>7/9/2017</u>, Register <u>223</u>) Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165 AS 08.80.030

12 AAC 52.400 is amended to read:

12 AAC 52.400. General guidelines for pharmacies. A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, *"Facility Standards for Pharmacies,"* dated <u>November 2016</u> [FEBRUARY 2008], and incorporated by reference in this section. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 7/9/2017, Register 223) Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

a Rublisher; "Please delete the 2nd four agrage of the editor's note that follows 12 MAC 52.400. 10

12 AAC 52.450 is amended to read:

12 AAC 52.450. Prescription drug order records. (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained [IN NUMERICAL ORDER AND] in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug

orders by [KEEPING IN ITS FILE]

(1) keeping the original hard copy [WRITTEN] prescription drug order

presented by a patient;

(2) **keeping** a plain paper version of the prescription drug order received by

facsimile or digital electronic transmittal; [OR]

(3) keeping a prescription drug order put into writing either manually or

electronically by the pharmacist; or

(4) electronically storing and maintaining the prescription drug order in a

readily retrievable format. (Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am

7/9 /2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030

AS 08.80.157

12 AAC 52.460(a) is amended to read: 12 MAC 52.460(a) is amended to read: 12 MAC 52.460(a) is amended to read: 12 Maguage of 12 Mac 52.460 (a) is uncleanged. III

(a) Before a pharmacist may fill a prescription drug order, the pharmacist shall obtain the-

Tollowing information."

(9) if a written or hard copy prescription drug order, the prescribing

practitioner's handwritten, digital, electronic, or stamped signature; [AND] 12 MAC 52.460 (2) (10) is mended to readi (10) if a [FACSIMILE] prescription drug order is received by the pharmacy as

a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped

signature, or authorized agent's signature; and 12 AAC 52.460(a) is amended by adding a new paragraph to read; (11) if the prescription drug order is signed by an authorized agent it mus include the name of the prescribing practitioner. (Eff. 1/16/98, Register 145; am 9/11/2010, Register 195; am 9/17/2011, Register 199; am

DOL File#JU2017200015-(Adopted 3/3/2017)

11/16/2012, Register 204; am _7/ 9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500(b) is amended to read:

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. <u>The transfer must be communicated</u> <u>directly between two licensed pharmacists.</u>

12 AAC 52.500(c) is amended to read:

(c) Original prescription drug order information for noncontrolled substances may be transferred verbally, electronically, or **Sia** facsimile between pharmacies without limitation up to the number of originally authorized refills.

12 AAC 52.500(d) is amended to read:

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

(1) **if transferred verbally,** the transfer shall be communicated directly between two licensed pharmacists;

(2) both the original and the transferred prescription drug order must meet the

requirements of 12 AAC 52.450(a);

(3) the pharmacist transferring the prescription drug order information shall

(A) repealed / / / WRITE "VOID" ON THE FACE OF THE

TRANSFERRED PRESCRIPTION DRUG ORDER; AND

-DOL File#JU2017200015 (Adopted 3/3/2017) 4

(B) record [ON THE REVERSE SIDE OF THE TRANSFERRED

PRESCRIPTION DRUG ORDER] the following information:

(i) name, address, and if a controlled substance, the DEA

registration number of the pharmacy receiving the prescription drug order

information;

(ii) name of the pharmacist receiving the prescription drug order

information;

(iii) name of the pharmacist transferring the prescription drug

order information; and

(iv) date of the transfer;

(4) the pharmacist receiving the transferred prescription drug order information

shall

(A) repeated /// WRITE "TRANSFER" ON THE FACE OF THE TRANSFERRED PRESCRIPTION DRUG ORDER; AND?
(B) record [ON THE TRANSFERRED PRESCRIPTION DRUG
ORDER] the following information:
(i) original date of issue and date of dispensing, if different
from the date of issue;
(ii) original prescription drug order number and the number
of refills authorized on the original prescription drug order;
(iii) number of valid refills remaining and the date of the last refill;
(iv) name, address, and if a controlled substance, the DEA
registration number of the pharmacy transferring the prescription drug order

information; and

_DOL_File#JU2017200015 (Adopted 3/3/2017) 5

v) name of the pharmacist transferring the prescription drug order

information; and

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further refills.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030

The introductory language of 12 AAC 52.585(a) is repealed and readopted to read:

(a) Before dispensing a prescription for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services must personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

(Eff. 1/16/98, Register 145; am 5/15/2004, Register 170; am <u>7/9/2017</u>, Register 223) Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52 is amended by adding a new section to read:

12 AAC 52.992. Independent administration of vaccines and related emergency

medications. (a) Before a pharmacist may independently administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist must

-DOL File#JU2017200015 (Adopted 3/3/2017), 6

1) successfully complete a course accredited by the Accreditation Council for

Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

(A) basic immunology, vaccine, and immunization protection;

(B) diseases that may be prevented by vaccination or immunization;

(C) current Centers for Disease Control and Prevention CDC

immunization schedules;

(D) vaccine storage and management;

(E) informed consent;

(F) physiology and techniques for administration of immunizations;

(G) pre-immunization and post-immunization assessment and counseling;

(H) immunization reporting and records management; and

(I) identifying, responding to, documenting, and reporting adverse

(CPR) and automated electronic defibrillator (AED) training; and (3) a pharmaeist who has not administered a vaccine within the past 10 years must complete a course as described in (a)(1) of this section before administering a vaccine; (4) pharmaeist must adhere to 12 AAC 52.320(continuing education requirements: (b) A pharmacy from which a pharmacist administers a human vaccine or related

emergency medication under this section

(1) must stock the following emergency medications in an emergency medication kit which is separate from the regular dispensing inventory, and which is carried by the pharmacist if providing off-site immunizations:

DOL File#JU2017200015 (Adopted 3/3/2017)

(A) oral and injectable diphenhydramine; and
 (B) adult and pediatric autopinject epinephrine device, or injectable

epinephrine;

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed and which:

(A) designates either the pharmacist in charge (PIC) or an assigned

vaccine coordinator who will be responsible for maintaining the policy and procedures

manual;

(B) documents that the policy and procedures manual has been reviewed

and updated annually;

the CDC's and FDA's (C) address how vaccine related adverse reactions are to be reported to the Vaccine Adverse Event Reporting System (VAERS);

> (D) addresses proper vaccine storage, handling, and maintenance, including maintaining manufacturer recommended temperatures during transportation of vaccines;

(E) addresses proper disposal of used or contaminated supplies;
 (F) contains a written emergency protocol for handling accidental needlesticks and adverse reactions including the administration of emergency related medications; and

(G) details how records must be kept;

(3) must have access to the latest edition of the CDC's Epidemiology and

Prevention of Vaccine-Preventable Diseases as a reference; and

(4) must display each pharmacist's certification of completing the immunization (a)()) of course described in this section.

"DOL File#JU2017200015 (Adopted 3/3/2017) 8

(c) Before administering an immunization or related emergency medication, a pharmacy

intern shalle wust

(1) have completed an ACPE approved immunization course or other comparable

accredite

(2) maintain certification of completing an adult and pediatric cardiopulmonary

(2) maintain certification a completing an addit and pediatric cardioputnionary

resuscitation (CPR) program and automated dectronic defibrillator (AED) training; and

(3) be under the direct supervision of a pharmacist who has met the requirements

of this chapter.

(d) A pharmacist administering a vaccine must provide the patient or the patient's agent

the current vaccine information statement (VIS) issued by the CDC for each vaccine

administered.

DOI_File#JU2017200015

(e) A pharmacist or intern independently administering a vaccine must comply with

- 1	4	inistrator of the vaccin	3 and	(pharmacist)
the prescribe			N .	ι Λ
(g) H	ailure to comply wit	th this section constitut	es unprofessional co	nduct and is a basis
for the impo	sition of disciplinary	sanctions under AS 0	3.01.075. (Eff. <u>7/</u>	9 12017, Register
223)				
Authority:	AS 08.01.075	AS 08.80.168	AS 08.80.480	
	AS 08.80.030	AS 08.80.261		

MEMORANDUM

Hon. Byron Mallott To: Lieutenant Governor

State of Alaska Department of Law

Date: June 9, 2017

File No.: JU2017200015

Tel. No.: 465-3600

From: Steven C. Weaver Sr. Assistant Attorney General and Assistant Regulations Attorney Legislation and Regulations Section

Re: Board of Pharmacy regulations re: pharmacist interns, prescription drug order records, facility standards, patient counseling, and administration of vaccines or related emergency medication (12 AAC 52.120(b)(3)(A); 12 AAC 52.210(1); 12 AAC 52.320(e); 12 AAC 52.400; 12 AAC 52.450; 12 AAC 52.460(a)(9)-(11); 12 AAC 52.500; 12 AAC 52.585(a); 12 AAC 52.992)

We have reviewed the attached regulations from the Board of Pharmacy against the statutory standards of the Administrative Procedure Act. I have reviewed this project under a general delegation dated December 5, 2014 from the Regulations Attorney. The regulations update requirements regarding pharmacist interns, prescription drug order records, facility standards, and patient counseling; establish new requirements, including education requirements, regarding independent administration of vaccines or related emergency medication; and update continuing education requirements to address those new requirements.

We find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

The January 10, 2017 public notice and the March 3, 2017 certification of adoption order both state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

Hon. Byron Mallott, Lieutenant Governor Our file: JU2017200015 June 9, 2017 Page 2

We have made some technical corrections to the regulations in accordance with AS 44.62.125, as shown on the attached copy.

SCW

cc w/enc: (via email)

Leif Holm, PharmD, Chair Board of Pharmacy (via e-mail through Jun Maiquis)

Micaela Fowler, Regulations Contact Department of Commerce, Community, and Economic Development

Janey Hovenden, Director Division of Corporations, Business, and Professional Licensing Department of Commerce, Community, and Economic Development

Jun Maiquis, Regulations Specialist Division of Corporations, Business, and Professional Licensing Department of Commerce, Community, and Economic Development

Donna Bellino Division of Corporations, Business, and Professional Licensing Department of Commerce, Community, and Economic Development

Megyn A. Greider, Assistant Attorney General Commercial and Fair Business Section

MEMORANDUM

To: The Honorable Byron Mallott Lieutenant Governor

Susan R. Pollard Malfollul From: Chief Assistant Attorney General and Regulations Attorney Legislation and Regulations Section

State of Alaska Department of Law

Date: December 5, 2014

Tel. No.: 465-3600

Re: Delegation of Authority for **Regulations Matters**

In my absence, when I am traveling or otherwise out of the office, Senior Assistant Attorney General and Assistant Regulations Attorney Steven C. Weaver is designated as Acting Regulations Attorney. Under this delegation, Steve Weaver has my full authority under AS 44.62 to conduct the legal review of regulations or take necessary actions as Acting Regulations Attorney.

This delegation is effective immediately and is in effect until revoked by me.

If you have any questions, please let me know.

SRP/pav

Scott Meriwether, AAC Coordinator cc: Office of the Lt. Governor

> Jim Cantor, Deputy Attorney General **Civil Division**

Nancy Gordon, Statewide Office Chief **Civil Division**

Steven C. Weaver, Sr. Assistant Attorney General and Assistant Regulations Attorney Legislation and Regulations Section

Cori Mills, Assistant Attorney General Legislation and Regulations Section

Linda Miller, Legal Editor Legislation and Regulations Section

Lisa Rickey, Legal Editor Legislation and Regulations Section

NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY, AND RELATING TO THE ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS IN THE REGULATIONS OF THE BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy proposes to update various regulations relating to the requirements for a pharmacy intern license, pharmacist duties, continuing education requirements for a pharmacist administering vaccines or related emergency medications, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and establishing standards for the independent administration of vaccines and related emergency medications.

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52, of the Alaska Administrative Code including the following:

- 1. **12 AAC 52.120. Review of pharmacist intern license application**, is proposed to be changed to alter the requirements for a pharmacist intern license.
- 2. **12 AAC 52.210. Pharmacist duties,** is proposed to be changed to alter the provisions related to duties that may only be performed by a pharmacist.
- 3. 12 AAC 52.320. Continuing education requirements for pharmacists, is proposed to be changed to alter the continuing education requirements for a pharmacist administering vaccines or related emergency medications.
- 4. **12 AAC 52.400. General guidelines for pharmacies**, is proposed to be changed to update the guidelines for pharmacies that the board adopts by reference.
- 5. 12 AAC 52.450. Prescription drug order records, is proposed to be changed to alter the prescription drug order records requirements by a pharmacy.
- 6. **12 AAC 52.460. Prescription drug order information,** is proposed to be changed to alter the information a prescription drug order must include before a pharmacist may fill it.
- 7. **12 AAC 52.500. Transfer of a prescription drug order**, is proposed to be changed to alter the provisions related to transfer of a prescription drug order between pharmacies.
- 8. **12 AAC 52.585. Mandatory patient counseling**, is proposed to be changed to alter the requirements for mandatory patient counseling by a pharmacist or pharmacy intern providing prescription services.
- 9. 12 AAC 52.992. Independent administration of vaccines and related emergency medications, is a proposed new section that establishes requirements for independent administration of vaccines and related emergency medications by a pharmacist.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Marilyn Zimmerman, Paralegal, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/184197, and using the comment link. The comments must be received not later than 5:00 p.m. on February 13, 2017. Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Marilyn Zimmerman, Paralegal, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at marilyn.zimmerman@alaska.gov. The questions must be received at least 10 days **before the end of the public comment period.** The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at

https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Marilyn Zimmerman at (907) 465-2532 or marilyn.zimmerman@alaska.gov not later than February 6, 2017 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Marilyn Zimmerman at (907) 465-2532 or marilyn.zimmerman@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0117.pdf.

A copy of material proposed for adoption by reference is available on the Alaska Online Public Notice System, or go to

https://www.commerce.alaska.gov/web/portals/5/pub/PHA_FacilityStandardsPharmacies_November.201 6.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. You should comment during the time allowed if your interests could be affected. Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.01.075; AS 08.80.005; AS 08.80.030; AS 08.80.110; AS 08.80.116; AS 08.80.147; AS 08.80.157; AS 08.80.165; AS 08.80.168; AS 08.80.261; AS 08.80.330; AS 08.80.480 **Statutes Being Implemented, Interpreted, or Made Specific:** AS 08.01.075; AS 08.80.005; AS 08.80.030; AS 08.80.110; AS 08.80.116; AS 08.80.147; AS 08.80.157; AS 08.80.165; AS 08.80.168; AS 08.80.261; AS 08.80.330; AS 08.80.480

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: 1/9/17

Jun Maiquis, Regulations Specialist Division of Corporations, Business and Professional Licensing

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION (AS 44.62.190(d))

- **1.** Adopting agency: Board of Pharmacy Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.
- 2. General subject of regulation: Pharmacist intern license application, pharmacist duties, continuing education requirements, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and independent administration of vaccines and related emergency medications.
- **3.** Citation of regulation: 12 AAC 52.120, 12 AAC 52.210, 12 AAC 52.320, 12 AAC 52.400, 12 AAC 52.450, 12 AAC 52.460, 12 AAC 52.500, 12 AAC 52.585, and 12 AAC 52.992.
- 4. Department of Law file number: To be assigned.
- 5. Reason for the proposed action: Compliance with new state statute; update and clarification of current regulations.
- 6. Appropriation/Allocation: Corporations, Business and Professional Licensing #2360.
- 7. Estimated annual cost to comply with the proposed action to: A private person: None. Another state agency: None. A municipality: None.
- 8. Cost of implementation to the state agency and available funding (in thousands of dollars): No costs are expected in FY 2017 or in subsequent years.
- The name of the contact person for the regulation: Donna Bellino, Licensing Examiner Alaska Board of Pharmacy Division of Corporations, Business and Professional Licensing Telephone: (907) 465-2589
 E-mail: donna.bellino@alaska.gov
- 10. The origin of the proposed action: Board of Pharmacy.

11. Date: 1/9

Prepared by:

Tallorem?

Jun Maiquis Regulations Specialist (907) 465-2537

STATE OF ALASKA

FIRST JUDICIAL DISTRIC

AFFIDAVIT OF NOTICE OF PROPOSED ADOPTION OF REGULATIONS AND FURNISHING OF ADDITIONAL INFORMATION

L Jun Maiguis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to

SS.

12 AAC 52.120, 12 AAC 52.210, 12 AAC 52.320, 12 AAC 52.400, 12 AAC 52.450, 12 AAC 52.460, 12 AAC 52.500, 12 AAC 52.585, and 12 AAC 52.992, dealing with requirements for a pharmacy intern license, pharmacist duties, continuing education requirements for a pharmacist administering vaccines or related emergency medications, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and establishing standards for the independent administration of vaccines and related emergency medications, has been given by being:

- 1. published in a newspaper or trade publication;
- 2. furnished to interested persons;
- 3. furnished to appropriate state officials;
- 4. furnished to the Department of Law, along with a copy of the proposed regulations;
- 5. electronically transmitted to incumbent State of Alaska legislators;
- 6. furnished to the Legislative Affairs Agency, Legislative Legal and Research Services;
- 7. posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1);
- 8. furnished electronically, along with a copy of the proposed regulations, to the Legislative Affairs Agency, the chair of the Labor and Commerce Committee of the Alaska Senate and House of Representatives, the Administrative Regulation Review Committee, and the legislative council.

As required by AS 44.62.190(d), additional regulations notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (5) and (6) of the list above. The additional regulations notice information also has been posted on the Alaska Online Public Notice System.

DATE: <u>5/1/17</u> Juneau, Alaska

NOTARY PUBLIC My Commission Expires With Office

Jun Maiguis, Regulations Specialist

My commission expires: with office

SUBSCRIBED AND SWORN TO before me	this day of M_{ay}	, 2017.
	hel Smith	
STATE OF ALASKA OFFICIAL SEAL Jedediah A. Smith	Notary Public in and for the State of Alaska	

STATE OF ALASKA

FIRST JUDICIAL DISTRICT

AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

) ss.

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy regulations on dealing with requirements for a pharmacy intern license, pharmacist duties, continuing education requirements for a pharmacist administering vaccines or related emergency medications, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and establishing standards for the independent administration of vaccines and related emergency medications.

DATE:

Juneau, Alaska

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this <u>1</u> day of <u>May</u>, 2017.



Notary Public in and for the State of Alaska My commission expires: <u>...the office</u>

268972 0001398503 \$592.64 RECEIVEC Juneau JAN 1 3 2017

CBPL

AFFIDAVIT OF PUBLICATION

1.

2.

3.

4.

5.

STATE OF ALASKA

THIRD JUDICIAL DISTRICT

Emma Dunlap

being first duly sworn on oath deposes and says that he/she is a representative of the Alaska Dispatch News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

January 10, 2017

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed

Subscribed and sworn to before me this <u>10th</u> day of <u>January</u>, <u>2017</u>

Notary Public in and for The State of Alaska. Third Division Anchorage, Alaska MY COMMISSION EXPIRES

State of Alaska ion Expires Feb 23, 201

NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY, AND RELATING TO THE ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS IN THE REGULATIONS OF THE BOARD OF PHARMACY

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52, of the Alaska Administrative Code including the following:

12 AAC 52.120. Review of pharmacist intern license application, is proposed to be changed to alter the requirements for a pharmacist intern license.

----- abarmaclet duties, is proposed to be

ONA AJTZNOM IH OT JAJH JAA



STATE OF ALASKA

FIRST JUDICIAL DISTRICT

AFFIDAVIT OF BOARD ACTION

SS.

I, Donna Bellino, Licensing Examiner for the Board of Pharmacy, being duly sworn, state the following:

The attached motion dealing with requirements for a pharmacy intern license, pharmacist duties, continuing education requirements for a pharmacist administering vaccines or related emergency medications, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and establishing standards for the independent administration of vaccines and related emergency medications was passed by the Board of Pharmacy during its March 2-3, 2017 teleconference meeting.

Date: 💾 Alaska

Donna Bellino, Licensing Examiner

SUBSCRIBED AND SWORN TO before me this 25th day of April _____, 2017.



Notary Public in and for the

State of Alaska My commission expires: WHO DFFICE

1	STATE OF ALASKA
2	DEPARTMENT OF COMMERCE, COMMUNITY AND
3	ECONOMIC DEVELOPMENT
4	DIVISION OF CORPORATIONS,
5	BUSINESS & PROFESSIONAL LICENSING
6	DRAFT
7	BOARD OF PHARMACY
8	MINUTES OF MEETING
9	<u>March 2-3, 2017</u>
10	
11	By authority of AS 08.01.070(2) and in compliance with the provisions of
12	Article 6 of AS 44.62, a scheduled teleconference meeting of the Board of
13	Pharmacy was held via WebEx Teleconference March 2-3, 2017 at the State
14	Office Building 333 Willoughby Ave., 9th Floor Conference room B.
15	
16	These minutes were prepared by the staff of the Division of
17	Corporations, Business and Professional Licensing. The minutes have
18	not been reviewed or approved by the Board of Pharmacy.
19	
20	The meeting was called to order by Chair, Leif Holm at 9:08 a.m.
21	
22	Call to Order/Roll Call
23	
24	Board Members Present constituting a quorum:
25	
26	Leif Holm, PharmD, North Pole – Chair
27	Richard Holt, PharmD, Wasilla – Vice Chair
28	Anne Gruening, Public Member, Juneau - Secretary
29	Phil Sanders, RPh, Soldotna
30	James Henderson, RPh, Soldotna
31	Lana Bell, RPh, Anchorage
32	
33	Not in Attendance:
34	Taryl Giessel, Public Member, Eagle River
35	
36	Attending from the Division of Corporations. Business and Professional
37	Licensing were:
38	
39	Donna Bellino, Licensing Examiner – Juneau
40	Janey Hovenden, Director - Juneau
41	Brian Howes, Investigator – Anchorage
42	
43	<u>Visitors Present via teleconference –</u>
44	Greg Estep, PharmD – Walgreens
45	Adam Chesler, PharmD – Telepharm.com

DRAFT Alaska Board of Pharmacy Minutes of Meeting March 2-3, 2017 Page 9 of 22

330	<u>AGENDA ITEM 1 – Regulation Review –</u>
331 332	The Board reviewed written public comments received for changes to the following
333	pharmacy regulations sent out for public comment:
334	pharmacy regulations sent out for public comment.
335	12 AAC 52.120 Review of pharmacist intern license application
336	12 AAC 52.210 Pharmacist Duties
337	12 AAC 52.320 CE Requirements for Pharmacists
338	12 AAC 52.400 General Guidelines for pharmacists
339	12 AAC 52.450 Prescription drug orders
340	12 AAC 52.460 Prescription drug order information
341	12 AAC 52.500 Transfer of prescription drug order
342	12 AAC 52.585 Mandatory patient counseling
343	12AAC 52.992 Independent administration of vaccines and related emergency
344	medications
345	
346	After review and discussion from the comments received for the 9 regulations the
347	board:
348	
349	On a motion duly made by Mr. Holt, seconded by Ms. Gruening and approved
350	unanimously, it was
351	
352	RESOLVED based on the review of public comment from proposed
353	regulations the Board adopted:
354	
355	12 AAC 52.120 Review of a pharmacist intern license application (3) (b)
356	(A) is adopted and is amended to read: enrolled in a college of
357	pharmacy accredited by ACPE
358	42 AAC F2 240 Discuss sist duties (4) a daute daw daw out dad to word
359 360	12 AAC 52.210 Pharmacist duties (1) adopted and amended to read: (1) Receiving an oral prescription drug order
300	(1) Receiving an oral prescription drug order
361	12 AAC 52. 320 Continuing Education Requirements for Pharmacists
362	is adopted and amended by adding:
363	(e) A pharmacist administering vaccines or related emergency
364	medications under 12 AAC 52.992 shall certify having completed one
365	hour of Accreditation Council for Pharmacy Education (ACPE) approved
366	continuing education specific to immunizations, vaccines, or vaccines
367	as part of the 30 contact hours of continuing education required under
368	(a) of this section.
369	

370	12 AAC 52.400 General Guidelines for Pharmacies is adopted and
371	amended to read: <i>"Facility Standards for Pharmacies," dated</i> <u>November</u>
372	<u>2016</u>
373 374	12 AAC C2. AEQ Descentistion David Order Descends is adopted and
374 375	12 AAC 52. 450 Prescription Drug Order Records is adopted and amended to read (b) 1-4
375	(1) <u>keeping the original hard copy prescription drug order presented by a</u>
370	patient:
378	(2) <u>keeping a plain paper version of the prescription drug order received by</u>
379	facsimile or digital electronic transmittal;
380	(3) <u>keeping a prescription drug order put into writing either manually or</u>
381	electronically by the pharmacist: or
382	(4) <u>electronically storing and maintaining the prescription drug order in a</u>
383	readily retrievable format.
303	readily retrievable format.
384	12 AAC 52.585 Mandatory patient counseling (A) – The introductory
385	language of 12 AAC 52.585 is repealed and readopted to read:
386	
387	(a) Before dispensing a prescription for the first time for a new patient of the
388	pharmacy, or a prescription for a new medication for an existing patient of
389	the pharmacy, or a change in the dose, strength, route of administration, or
390	directions for use of an existing prescription previously dispensed for an
391	existing patient of the pharmacy, the pharmacist or pharmacy intern
392	providing prescription services must personally counsel each patient or
393	the patient's agent on matters considered significant in the pharmacist's
394	professional judgement. The counseling may include
395	12 AAC 52.460 Prescription Drug Order information (a)
396	The Board would like to re-amend and resend out for public comment if
397	deemed necessary to include changes to:
398	-
399	(9) if a written or <u>hard copy</u> prescription drug order, the prescribing
400	practitioner's <u>handwritten, digital, electronic, or stamped signature</u>
401	
402	(10) if a prescription drug order <u>is received by the pharmacy as a</u>
403	<u>facsimile,</u> the prescribing practitioner's <u>handwritten, digital, electronic</u>
404	<u>or stamped signature, or authorized agent's signature; and</u>
405	
406	(11) if the prescription drug order is signed by an authorized agent it
407	must include the name of the prescribing practitioner.
408	

409	12 AAC 52. 500 Transfer of a Prescription Drug Order is adopted and
410	re-amend (d) #5 that it is not to be repealed and add back in
411	[When a prescription drug order is transferred, the transferring
412	pharmacy may not issue any further refills].
413	
414	12 AAC 992 Independent administration of vaccines and related
415	emergency medications is adopted and would like to re-amend (a)
416	(1) (D) to read vaccine storage and management, and (I) to read identifying,
417	responding to, documenting, and reporting adverse responses
418	(2) <u>add</u> in maintain certification and <u>keep documentation</u> in adult and
419	pediatric cardiopulmonary resuscitation (CPR) and automated electronic
420	defibrillator (AED) training; and
421	(3) a pharmacist who has not administered a vaccine within the past 10 years
422	must complete a course as described in (a)(1) of this section before
423	administering a vaccine.
424	add (4) Referral - Pharmacist must adhere to 12 AAC 52.320 Continuing
425	Education Requirements.
426	
427	(b) A pharmacy from which a pharmacist administers a human vaccine or
428	related emergency medication under this section.
429	(d) A pharmacist administering a vaccine must provide the patient, or the
430	patient's agent, the current vaccine information statement (VIS) issued by
431	the CDC for each vaccine administered.
432	SB 74 REGULATIONS -
433	
434	The Board reviewed and discussed the preliminary draft of SB74 regulations. The
435	discussion began with the Board reviewing the definition of what a dispenser is

The Board reviewed and discussed the preliminary draft of SB74 regulations. The
discussion began with the Board reviewing the definition of what a dispenser is
versus what a practitioner is, and the need for a pharmacist to monitor the PDMP
for each CII & CIII prescription dispensed.

438

This is not what the Board intended and per guidance Mr. Holm received from AAG
Greider who advised that the Board should write the regulations as they would like
for them to be and if there is a problem with what is submitted they will let the
Board know.

443

444 The definition of Practitioner is in statute and cannot be changed so when 445 practitioner is used the definition can be referred to. The Board's desire would not 446 be to include pharmacists.

447